

REMARKS

The amendments to the claims do not add new matter. Claim 11, as amended, is directed to the embodiment described in the specification at e.g., page 9, lines 10-23, and exemplified in FIGs 10A-10B. The preamble of claim 11 uses the term “assembled” which more accurately describes the embodiment being claimed. Claim 11, which has been amended at line 2 to recite “adjacent vertebrae,” has support for the term “adjacent vertebrae” later in the claim. In conformity with the description of the juxtaposition of the “first section” and the “second section” of FIGs 10A and 10B, the references to the “first” end and the “second” end of the elongated body have been switched.

Claim 12 was amended by deleting some of the alternatives. Claim 13, which recites that the two or more threaded sections of cortical bone have “joining holes” for insertion of the pins, is supported throughout the specification, including FIG 10A where they are shown but not numbered. Claims 14, 16, and 17-19 have been clarified.

Claim 20 has been amended to claim the specific embodiment of FIG 10A, having “two pins” which is shown as assembled in FIG 10B. In conformity with the description of the juxtaposition of the “first section” and the “second section” of FIGs 10A and 10B, the references to the “first” end and the “second” end of the elongated body have been switched.

Claims 22 and 23 deleted some extraneous language.

New claim 25, which recites that the “two pins” are “two cortical bone pins,” is supported throughout the specification, including at page 9, line 14 (“cortical bone”).

New claim 26, which recites that the second end of the elongated body is “slotted,” is supported by the disclosure at page 9, line 16 (“The second section has a slot 1015 formed thereon . . .”).

For all these reasons, the amendments to the claims do not add new matter.

Summary of the Bases for Rejection

Claims 1-4, 9, and 17-19, 23 are rejected under 35 U.S.C. § 103(a), as being allegedly unpatentable over U.S. Patent No. 6,210,412 (“Michelson”) in view of U.S. Patent No. 6,277,149 (“Boyle”).

Claims 15 and 16 are rejected under 35 U.S.C. § 103(a), as being allegedly anticipated by U.S. Patent No. 6,111,164 (“Rainey”) in view of U.S. Patent No. 6,210,412 (“Michelson”).

Claims 5, 6, 8 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,210,412 (“Michelson”) in view of U.S. Patent No. 6,277,149 (“Boyle”) and further in view of U.S. Patent No. 6,111,164 (“Rainey”).

Claim 10 is rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,210,412 (“Michelson”) in view of U.S. Patent No. 6,277,149 (“Boyle”) and further in view of U.S. Patent No. 6,174,311 (“Branch”).

Claims 11-14, 20-22, 24 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 6,210,412 (“Michelson”) in view of U.S. Patent No. 6,277,149 (“Boyle”) and further in view of U.S. Patent No. 6,258,125 (“Paul”).

The Applicants will address each of these bases for rejection in Sections I-V, respectively, which follow.

I. 35 U.S.C. § 103(a) over Michelson in view of Boyle

Claims 1-4, 9, and 17-19, 23 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,210,412 (“Michelson”) in view of U.S. Patent No. 6,277,149 (“Boyle”). Claims 1-10 have been cancelled, claims 17-19 reflect dependency upon claim 11, and claim 23 has been amended to add the elements of claim 24, now cancelled. Therefore, the rejection of claims 1-4 and 9 has been rendered moot. The Applicants also believe that in light of the amendment, changing dependency to claim 11, the rejection of claims 17-19 and 23 has also been rendered moot.

One of the criteria that must be met in order to establish a *prima facie* case of obviousness is that the prior art references must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination must be found in

the prior art. *See In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2142, 2143, and 2143.03. The Patent Office has acknowledged that neither Michelson nor Boyle teaches an implant comprising two sections. *See* Official Action, page 6 (“...it is noted that the above combinations of references [Michelson and Boyle] teach all of the limitations, **except for an implant comprising two separate sections**, as claimed by applicant.”); emphasis added in bold. In the present case, claims 17-19, as amended, are directed to an assembled implant comprising two or more separate sections that are joined together. Claim 23 is directed to a method for fusing vertebrae that utilizes an assembled implant comprising “two threaded sections of cortical bone connected in tandem by two bone pins to form an elongated body....” Because Michelson and Boyle fail to teach an assembled implant such as recited in claims 17-19 and 23, Applicants respectfully request withdrawal of this basis of rejection.

Additionally, as discussed in Section V, below, the Applicants respectfully believe claims 17-19 and 23 are not rendered unpatentable by Michelson and Boyle further in view of Paul, as applied by the Patent Office to claims 11-14, 20-22 and 24.

II. 35 U.S.C. § 103(a) over Rainey in view of Michelson

Claims 15 and 16 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,111,164 (“Rainey”) in view of U.S. Patent No. 6,210,412 (“Michelson”). Claim 15 has been cancelled herein. Therefore, the rejection of claim 15 has been rendered moot. Claim 16 has been amended to reflect dependency on claim 11 and to recite an apparatus, rather than a method. Applicants also respectfully believe that the rejection of claim 16 is no longer applicable. Specifically, claim 16, which now recites dependency to claim 11, is directed to a biomedical implant that comprises two or more separate sections joined together. However, as noted above, the Patent Office acknowledges that Michelson does not teach or suggest a biomedical implant having two separate sections. Additionally, Rainey does not disclose such an implant. Rather, Rainey discloses a single-piece bone graft insert. *See* Rainey, Fig. 1A and 1C. Therefore, neither Michelson nor Rainey, either individually or in combination, teach or suggest the limitation to “two or more separate sections” of independent claim 11, or of claim 16

which depends therefrom. Applicants respectfully request the withdrawal of this basis for rejection.

III. 35 U.S.C. § 103(a) over Michelson in view of Boyle and Rainey

Claims 5, 6, and 8 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,210,412 (“Michelson”) in view of U.S. Patent No. 6,277,149 (“Boyle”) and further in view of U.S. Patent No. 6,111,164 (“Rainey”). Claims 5, 6 and 8 have been cancelled by amendment herein. Accordingly, this basis for rejection has been rendered moot.

IV. 35 U.S.C. § 103(a) over Michelson, U.S. Pat. 6,277,149 (Boyle) and U.S. Pat. 6,174,311 (Branch)

Claim 10 is rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,210,412 (“Michelson”) in view of U.S. Patent No. 6,277,149 (“Boyle”) and further in view of U.S. Patent No. 6,174,311 (“Branch”). However, claim 10 has been cancelled. Accordingly, this basis for rejection has been rendered moot.

V. 35 U.S.C. § 103(a) over Michelson, U.S. Pat. 6,277,149 (Boyle) and U.S. Pat. 6,258,125 (Paul)

Claims 11-14, 20-22, and 24 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Patent No. 6,210,412 (“Michelson”) in view of U.S. Patent No. 6,277,149 (“Boyle”) and further in view of U.S. Patent No. 6,258,125 (“Paul”). Claim 21 is cancelled herein and no longer subject to this basis for rejection.

As amended herein, independent claim 11 is drawn to an implant, composed of **two or more separate sections** that are joined together, that upon joining of the separate sections, comprises an elongated body with a continuously tapered and threaded surface. Claim 20 has been amended to incorporate the text of claim 21 (now cancelled) and is directed to an **assembled** implant comprising **“two threaded sections of cortical bone connected in tandem by two pins** to form a continuously tapered and threaded surface. . . .” Claim 23 has been amended to incorporate the text of claim 24 (now

cancelled) and is directed to a method for fusing vertebrae, wherein at least one step comprises the use of an **assembled** implant comprising “**two threaded sections of cortical bone connected in tandem by two pins** to form a continuously tapered and threaded surface. . . .”

The Patent Office contends that Michelson in view of Boyle teach “all of the limitations **except for an implant comprising two separate sections**, as claimed by applicant.” [Official Action, page 6 ; emphasis added in bold]. To make up for this deficiency, the Patent Office contends that “Paul et al., as best seen in FIGS 7, 9, and 11, and column 4, lines 40-57, evidence the use of an implant having two separate sections to allow smaller sections of allergenic bone to be used for the fabrication of an implant.” [Official Action at page 6]. While Paul does disclose the use of smaller sections of allogeneic bone in combination, Paul fails to teach or suggest the Applicants invention.

Specifically, Paul discloses in Figure 7 an implant having a “top portion 52 joined to a bottom portion 54.” [Paul at col. 4, lines 44-45.] The implant of Figure 7 of Paul has “top and bottom surfaces 56, 58 [that] have **ridges 60** that mate with **grooves 62** to **interlock** top and bottom portions 52, 54.” Consistent with Paul’s use of the terms “top” and “bottom” portions, the portions of the implant of FIGs. 7 and 8 are stacked and **interlocked** with the stress forces being vertical compression, such that there are no lateral stress forces on the pins holding the implant together. The pins are merely for alignment. The implant of FIG. 9 of Paul shows two separate implants, “[f]irst and second implants 70, 70” that are “provided with locking pins 74 which engage apertures 76 **to maintain the spatial relationship** between the first and second implants 70, 70’.” [Paul at col. 5, lines 17-23.] Thus, while the compression on the implants is vertical, the pins in FIG. 9 of Paul are merely for alignment.

The last figure of Paul that is relied upon by the Patent Office is FIG. 11. FIG. 11 discloses an implant 80 having “a top portion 82, a middle portion 84, and a bottom portion 86. As was the case for implant 80, the surfaces between the portions are mating surfaces with **interlocking surface features**, such as **ridges** and **grooves**. One or more pins preferably hold top, middle, and bottom portions 82, 84, 86 together.” [Paul at col. 5, lines 1-7; emphasis added in bold.] Thus, in both Figures 7 and 11 of Paul, the assembled implant requires interlocking surface features (ridges and grooves) which

absorb insertional stresses. The pins are used merely for alignment. Likewise in the dual implants of FIG. 9, the pins are used merely for alignment and not as stress bearing structures.

In contrast to the assembled implants of Paul which require interlocking features between opposing faces of assembled bone portions, the assembled allograft of Applicants' invention does not require interlocking features between the opposing faces of cortical bone portions. In Paul, any pins are merely for alignment. In contrast, in the Applicants' invention, the pins are also structural elements that can withstand torsional stress when the assembled screw is torqued into position between adjacent vertebrae. There is no teaching or suggestion in Paul, alone or in combination with Michelson and Boyle, to use pins as torsional elements, or to connect bone portions in tandem to create a larger implant. For this reason, the rejection of claims 11-14, 20, 22, and 24 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,210,412 ("Michelson") in view of U.S. Pat. 6,277,149 ("Boyle") and further in view of U.S. Pat. 6,258,125 ("Paul") is legally erroneous.

The Patent Office also does not present evidence of any motivation or teaching to combine the references to achieve the elements of the present claims. To establish a *prima facie* case of obviousness, "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings." MPEP §2143. The references, alone or in combination, fail to provide motivation or a suggestion to assemble an implant comprising two or more sections connected in tandem, without interlocking features, or that bone pins alone in such an implant would withstand the torsional strain. For this reason, it appears that the Patent Office has utilized hindsight reasoning to arrive at Applicants' present claims. *See, e.g., Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1376 (Fed. Cir. 2002) ("Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention."). Accordingly, Applicants respectfully request the withdrawal of this basis of rejection.

CONCLUSION

Claims 1-6 and 8-24 stand rejected. Claims 1-10, 15, 21, and 24 are cancelled herein. New claims 25-26 have been added. Accordingly, claims 11-14, 16-20, 22-23 and 25-26 are pending.

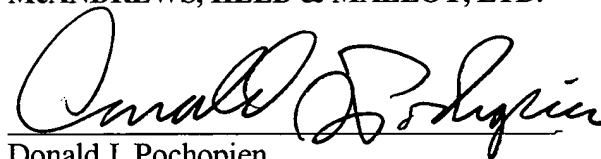
In view of the amendments and arguments provided herein, all bases for rejection of claims 11-14, 16-20, and 22-23 under 35 U.S.C. § 103(a) for alleged obviousness have been rebutted.

Claims 11-14, 16-20, 22-23 and 25-26 are in condition for allowance.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By:



Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants
500 West Madison Street
34th Floor
Chicago, Illinois 60661
(312) 775-8133

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